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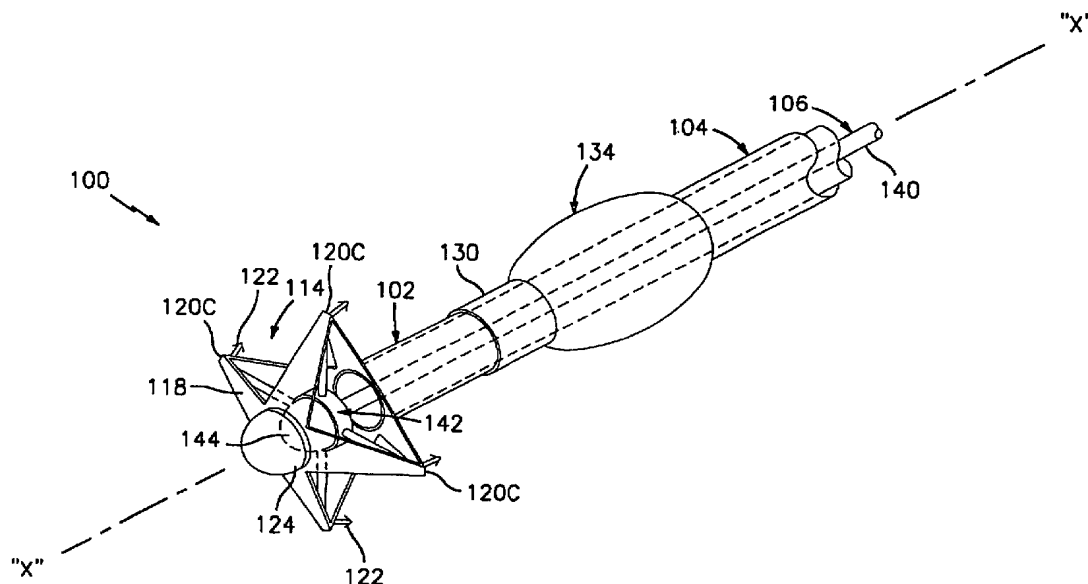
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(54) Title: METHOD AND APPARATUS FOR ANASTOMOSIS INCLUDING AN ANCHORING SLEEVE



(57) Abstract: Apparatus for performing a surgical anastomosis include a tubular body having an onion portion formed near the distal end of the tubular body. The apparatus includes a sleeve having a radius sized and dimensioned to slidably receive the tubular body therein. The apparatus includes a plunger assembly sized and dimensioned to be slidably received within the central lumen of the tubular body. The plunger assembly includes a distal end configured and adapted to deploy the onion portion.

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5 **METHOD AND APPARATUS FOR ANASTOMOSIS**
 INCLUDING AN ANCHORING SLEEVE

BACKGROUND

1. Technical Field

 The present disclosure relates to apparatus and methods for joining tissue portions
10 and, more particularly to anastomotic devices and methods for positioning and joining
body vessels using an anchoring sleeve.

2. Background of Related Art

 Anastomosis is the joining of two hollow or tubular structures. Certain body
15 conduits are generally cylindrical in configuration and have a circular cross-section.
When it is desired to suture such a conduit, typically for attachment to another body
conduit, sutures are placed around the circumference of the conduit in order to maintain
the patency of its lumen or channel. It can be appreciated that the sutures made on top of
the conduit (i.e., on the side facing the surgeon) are made relatively more easily than the
20 sutures made underneath the conduit (i.e., on the side facing away from the surgeon).

 The complexity of joining two body vessels is made manifestly apparent in a
surgical procedure referred to generally as a radical prostatectomy (i.e., a well established
surgical procedure for patients with localized prostatic carcinoma). In general, radical
prostatectomy procedures require the removal of cancerous tissue while preserving sexual
25 function and continence in the patient. There are two primary types of radical
prostatectomy approaches for the removal of prostate cancer, the retropubic approach and
the perineal approach.

 In the retropubic approach, a long up-and-down incision is made in the midline of
the abdomen from the navel to the pubic bone. After the lymph nodes have been
30 removed for study by the pathologist and a determination has been made to proceed with
the removal of the prostate gland, the space underneath the pubic bone is cleaned and
dissected and the removal of the entire prostate gland is generally begun at the end that is
farthest from the bladder, i.e., next to the external urethral sphincter. Next, the prostatic
urethra is divided, the prostatic urethra and the prostate gland through which it goes are

then pulled upwards toward the bladder while the dissection continues behind the prostate gland, separating it from the layer of tissue that is connected to the rectum on its other side. As the dissection continues between the prostate and the rectum, the seminal vesicles, which are behind the base of the bladder will be removed along with the prostate gland. Once the seminal vesicles are free, the entire prostate gland and the seminal vesicles are removed. The bladder neck is then stitched closed to a small enough diameter so that it is about the same size as the stump of the urethra from which the prostate was detached. The bladder neck is then pulled down into the pelvis and positioned against the urethral stump and stitched thereto. This stitching is done typically around a Foley catheter which has been inserted through the penis all the way into the bladder.

In the perineal approach, an inverted "U" shaped incision is made going right over the anus, with the center of the "U" about three centimeters above the margin of the anus. The prostate gland is then freed from its surrounding structures by gentle dissection, and the urethra at the end of the prostate farthest from the bladder is isolated and divided. The bladder neck is freed from the prostate, and, once the prostate gland has been removed and the bladder neck has been closed sufficiently so that the size of its opening approximates the size of the urethral opening, the urethra and the bladder neck are stitched together. Once again, a Foley catheter is left in place postoperatively for about two weeks.

In each of the above described procedures, it is the attachment of the urethral stump to the bladder neck which is particularly difficult and complex. This difficulty is complicated by the tendency of the urethral stump to retract into adjacent tissue. As a result, considerable time and effort must be expended to re-expose the urethral stump and begin the re-anastomosis procedure. Further complicating this procedure is the fact that the urethral stump is hidden beneath the pubic bone thus requiring that the surgeon work at a difficult angle and in positions that are uncomfortable and limiting.

Various devices have been proposed for facilitating this procedure. In U.S. Pat. No. 5,591,179, issued to Edelstein, there is disclosed a suturing device including a shaft with portions defining an interior channel extending between a proximal and a distal end of the shaft. This channel includes a generally axial lumen which extends to the proximal end of the shaft and a generally transverse lumen which extends from the axial lumen distally outwardly to an exit hole at the outer surface of the shaft. A needle and suture can be back loaded into the transverse lumen of the channel while a generally non-

compressible member can be movably mounted in the axial lumen of the channel. At the proximal end of the shaft a handle is provided with means operative to push the member distally through the lumen to deploy or expel the needle.

5 In U.S. Pat. No. 4,911,164, issued to Roth, there is disclosed a suture guide with a curved distal portion. The distal portion of the suture guide has a plurality of exterior axial grooves which can be used to align and guide a curved needle and attached suture. In order to drive the urethral stump to an accessible position, the device is provided with a plurality of outwardly extendable members which engage the lumen of the urethra. These members make it possible to push the urethral stump into approximation with the bladder neck.

10 In U.S. Pat. No. 5,047,039, issued to Avant et al., there is disclosed a surgical device for the ligation of a dorsal vein and subsequent anastomosis. This device contains a pair of enclosed needles each having an attached suture which needles may be driven from the shaft of the device into adjacent tissue.

15 In general, none of the devices disclosed in the prior art references above is simple to use or makes the anastomosis of the urethral stump to the bladder neck easier. As such, each surgical procedure using prior art devices continues to be time consuming and requires great skill in order to be performed. Accordingly, the need exists for anastomosis devices which overcome the drawbacks of the prior art devices and which are quick and simple to use.

SUMMARY OF THE INVENTION

Apparatus and methods for performing a surgical anastomotic procedure are disclosed herein. Apparatus according to the present disclosure include a tubular body having a proximal end, a distal end and an onion portion formed near the distal end of the tubular body for engaging a first body vessel. The onion portion has a first position within a radial dimension of the tubular body and a second position outside the radial dimension of the tubular body. The apparatus includes a sleeve having an expandable cuff for engaging the second body vessel. The sleeve has a lumen for receiving the tubular body. The apparatus includes a plunger assembly for being recalled in the tubular body. The plunger assembly has a distal end arranged for deploying the onion portion from the first position to the second position.

Preferably, the tubular body has a first position in which the onion sleeve portion is substantially co-linear with or within the radial dimension of the tubular body and a

second position in which the onion sleeve portion is deployed transversely with respect to the tubular body. The tubular body desirably has a radius and defines a central lumen having a radius.

5 In accordance with an embodiment of the present disclosure, the onion sleeve portion includes a plurality of longitudinally oriented slots defining a plurality of ribs. The ribs desirably include at least one flexure line. Preferably, each rib includes a distal flexure line, a proximal flexure line and an intermediate flexure line between the distal and proximal flexure lines. Most preferably, each intermediate flexure line is a double articulating joint. In is envisioned that the onion sleeve portion defines a radius about the
10 intermediate flexure lines which is less than the radius of the tubular body.

In accordance with the present disclosure at least one of the plurality of ribs includes a barb extending therefrom for engaging the first body vessel. Preferably, each barb does not extend beyond the radius of the tubular body while the onion sleeve portion is in the first position. More preferably, each barb is formed on the rib at a location
15 between the proximal flexure line and the intermediate flexure line. It is contemplated that each barb is oriented in a substantially proximal direction when the onion sleeve portion is in the second position.

In certain preferred embodiments, the onion portion has at least one expanded portion disposed outside the radial dimension of the tubular body when the onion portion is in the second position. The onion portion may have two expanded portions for
20 engaging the first body vessel therebetween.

In accordance with an alternative embodiment of the present disclosure, it is envisioned that each rib of the onion sleeve portion includes a distal flexure line, a proximal flexure line, a pair of central flexure lines, a first intermediate flexure line
25 between the distal the pair of central flexure lines and a second intermediate flexure line between the proximal flexure lines and the central flexure lines. Preferably, each first intermediate flexure line is a double articulating joint. More preferably, the onion sleeve portion defines a radius about the first intermediate flexure lines which is less than the radius of the tubular body.

30 It is envisioned that at least one of the plurality of ribs includes a barb extending therefrom, wherein each barb does not extend beyond the radius of the tubular body while the onion sleeve portion is in the first position. It is contemplated that each barb is formed on the rib at a location between the first intermediate flexure lines and the central

flexure lines. Preferably, each barb is oriented in a substantially proximal direction when the onion sleeve portion is in the second position.

It is further contemplated that the head portion of the plunger assembly is provided with an engaging element configured and adapted to selectively couple with an engaging element provided at the distal end of the tubular body.

A preferred method of joining a first body vessel and a second body vessel comprises passing an apparatus through the second body vessel, the apparatus having an onion portion so that the onion portion is received in the first body vessel. The onion portion is deployed so that the onion portion moves to a position outside the radial dimension of the tubular body. The first body vessel and second body vessel are approximated and joined.

The method further includes the step of expanding an expandable cuff to engage the second body vessel. The apparatus may include a sleeve having the expandable cuff and the method may include moving the tubular body and the sleeve with respect to one another so as to approximate the first and second body vessels. The apparatus may have a plunger assembly for deploying the onion portion and the method may include advancing the plunger assembly so as to deploy the onion portion. The position of the tubular body and sleeve are desirably secured with respect to one another.

These and other features of the apparatus and method disclosed herein, will become apparent through reference to the following description of embodiments, the accompanying drawings and the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the disclosure and, together with the general description given above and the detailed description of the embodiments given below, serve to explain the principles of the present disclosure.

FIG. 1 is a perspective view of an anastomosis apparatus, in accordance to an embodiment of the present disclosure, shown in an insertion condition;

FIG. 2 is a perspective view of the anastomosis apparatus of FIG. 1, shown in a deployed condition;

FIG. 3 is a partial cross-sectional perspective view of a portion of a urinary system with the anastomosis apparatus of FIG. 1, shown in the insertion condition, and

illustrating the anastomosis apparatus being passed through a body lumen and entering a hollow body organ;

FIG. 4 is partial cross-sectional perspective view of the urinary system with the anastomosis apparatus of FIG. 1, with the radially expandable onion sleeve shown in a
5 deployed condition within the hollow body organ and the radially expandable cuff shown in a deployed condition within the body lumen;

FIG. 5 is a cross-sectional side elevational view of the apparatus of FIG. 1, depicting the approximation of the hollow body organ to the body lumen;

FIG. 6 is a perspective view of an anastomosis apparatus, in accordance to another
10 embodiment of the present disclosure, shown in an insertion condition; and

FIG. 7 is a cross-sectional side elevational view of the anastomosis apparatus of FIG. 6, depicting the approximation of the hollow body organ to the body lumen.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

15 Preferred embodiments of the presently disclosed anastomosis apparatus will now be described in detail with reference to the drawing figures wherein like reference numerals identify similar or identical elements. In the drawings and in the description which follows, the term “proximal”, as is traditional will refer to the end of the surgical device or instrument of the present disclosure which is closest to the operator, while the
20 term “distal” will refer to the end of the device or instrument which is furthest from the operator.

Referring now to FIGS. 1-5, an anastomosis apparatus, in accordance with the principles of the present disclosure, is shown generally as reference numeral 100. Although apparatus 100 offers significant advantages to a radical prostatectomy
25 procedure, it will be understood that the device is applicable for use in any anastomotic procedure where two body vessels are to be approximated and/or joined, including approximating and/or joining the urethra and bladder, intestinal portions of the body, blood vessels, and any other body vessels.

As seen in FIG. 1, apparatus 100 includes a tubular body 102, a sleeve 104
30 slidably received about tubular body 102 and a plunger assembly 106 slidably received within tubular body 102. Tubular body 102 includes a proximal end 108 and a distal end 110 and defines a central lumen 112 extending therethrough which central lumen 112 defines a central longitudinal axis “X”.

Tubular body 102 includes an expandable anchor or onion sleeve portion 114 formed near distal end 110. In accordance with the present disclosure, onion sleeve portion 114 includes a plurality of radially formed, longitudinally oriented, elongated slots 116. Slots 116 define a plurality of longitudinally oriented ribs 118, each desirably having a plurality of transverse flexure lines 120 formed along the length thereof or being otherwise flexible. Preferably, ribs 118 include a distal and a proximal flexure line 120A, 120B, respectively, and an intermediate flexure line 120C. In one preferred embodiment, intermediate flexure line 120C is a double articulating flexure line, i.e., a flexure line which can be bent in two directions.

10 In accordance with the present disclosure, onion sleeve portion 114 has a biased retracted position, as seen in FIG. 1, in which a radius of onion sleeve portion 114, about intermediate flexure lines 120C, is less than a radius of tubular body 102. Onion sleeve portion 114 has an unbiased expanded position, as seen in FIG. 2, in which the radius of onion sleeve 114, about intermediate flexure lines 120C, is greater than the radius of tubular body 102. In the embodiment shown, when onion sleeve portion 114 is in the expanded position, the portion of each rib 118 between intermediate flexure line 120C and proximal flexure line 120B is disposed at an angle with respect to the longitudinal "X" axis.

20 Onion sleeve portion 114 of tubular body 102 further desirably includes at least one barb 122 extending outwardly from each rib 118 and in a proximal direction. In accordance with the present disclosure, when onion sleeve portion 114 is in the retracted position, barbs 122 do not extend beyond the radial boundary of tubular sleeve 102. In this manner, barbs 122 do not interfere with the passage of tubular body 102 through sleeve 104. Further, in accordance with the present disclosure, when onion sleeve portion 25 114 is in the expanded position, it is preferred that barbs 122 are oriented substantially in a proximal direction and are substantially co-linear with the longitudinal "X" axis. While barbs 122 are preferred for penetrating body tissue, it is envisioned that the outer surface of rib 118 can be roughened in order to increase the gripping effect of rib 118 when in contact with body tissue.

30 It is contemplated that onion sleeve portion 114 and barbs 122 are made from a medical grade material, such as, for example, stainless steel or titanium, however, it is preferred that onion sleeve portion 114 and barbs 122 are made from a medical grade bio-absorbable material, such as, for example, polyglycolic acid (PGA) and/or polylactic acid (PLA).

As seen in the figures, distal end 110 of tubular body 102 is provided with a blunt end cap 124. However, tubular body 102 may have a distal end which opens into central lumen 112.

5 Sleeve 104 includes a distal end 130 and a proximal end (not shown) defining a lumen 132 extending therethrough. It is envisioned that distal end 130 of sleeve 104 can be tapered in order to facilitate passage of sleeve 104 through the body lumen. In accordance with the present disclosure, sleeve 104 includes an expandable cuff 134 provided near distal end 130 thereof. Preferably, expandable cuff 134 has a first position in which expandable cuff 134 has a radius which is less than or equal to a radius of sleeve
10 104 and a second position in which expandable cuff 134 has a radius which is greater than the radius of sleeve 104.

It is envisioned that sleeve 104 is provided with an inflation/deflation lumen (not shown) extending along the length thereof and which is in fluid communication with expandable cuff 134 through at least one access opening (not shown) formed in sleeve
15 104. In use, the inflation/deflation lumen is coupled to a source of inflation fluid (not shown) and a fluid is injected through the inflation/deflation lumen in order to inflate and expand cuff 134 to an expanded condition and thereby anchor or fix the placement of sleeve 104 within the body lumen. Concomitantly, withdrawal of the fluid used to inflate and expand cuff 134 will cause cuff 134 to deflate and thereby allow sleeve 104 to be
20 withdrawn from the body lumen.

Expandable cuff 134 is preferably fabricated from a medical grade polymer having suitable flexibility and structural integrity to withstand the forces associated with the inflation of cuff 134 and with the function of anchoring sleeve 104 within the body lumen.

25 At least one annular seal, i.e., an O-ring, (not shown) is desirably provided between tubular body 102 and sleeve 104. The annular seal prevents or reduces the possibility of fluids from passing between tubular body 102 and sleeve 104.

Plunger assembly 106 includes a shaft 140 having a distal end 142, a proximal end (not shown) and a head portion 144 operatively coupled to distal end 142. In the
30 embodiment shown, head portion 144 is preferably dimensioned to be received within central lumen 112 of tubular body 102. More preferably, head portion 144 defines a circular outer surface having an outer radius slightly smaller than the inner radius of tubular body 102

It is envisioned that the outer surface of head portion 144 is provided with a coupling element (not shown) configured and adapted to engage a corresponding coupling element (not shown) formed in either the inner surface of the distal end 110 of tubular body 102 or on the inner surface of end cap 124 of tubular body 102. It is contemplated that the coupling element formed on head portion 144 could be a helical thread which is configured and adapted to engage a corresponding helical thread formed on the inner surface of distal end 110 of the tubular body 102 at a location distal of onion sleeve portion 114. It is further contemplated that the coupling elements of head portion 144 and of distal end 110 of tubular body 102 may form a bayonet type coupling.

As will be described in greater detail below, in use, as plunger assembly 106 is distally advanced through central lumen 112 of tubular body 102, head portion 144 of plunger assembly 106 first engages the inner surface of ribs 118. As head portion 144 of plunger assembly 106 is further distally advanced, past onion sleeve portion 114, head portion 144 presses ribs 118 radially outward. In so doing, onion sleeve 114 goes from the biased retracted position to the unbiased expanded position, as discussed above. Head portion 144 is then further advanced until the coupling element of head portion 144 engages the coupling element formed at distal end 110 of tubular body 102.

It is envisioned that apparatus 100 be provided with a locking mechanism for securing tubular body 102 to sleeve 104 and to prevent their relative movement with respect to one another.

A preferred method of use and operation of anastomosis apparatus 100 in a radical anastomotic procedure will now be described in greater detail with reference to FIGS. 1-5 and in particular with reference to FIGS. 3-5. Apparatus 100 can be used in either the retropubic or the perineal prostatectomy approaches. With the prostate removed, the bladder neck "N" of the bladder "B" is first reconstructed by everting the inner mucosal lining of bladder "B" and suturing it down to the outer wall of bladder "B" using known surgical techniques. Likewise, urethral stump "S" of urethra "U" is reconstructed by everting the inner mucosal lining of urethral stump "S" and suturing it down to the outer wall of urethra "U", using known surgical techniques.

Preferably, with bladder neck "N" reconstructed, bladder neck "N" is sized to properly accommodate and retain distal end 108 of tubular body 102 within bladder "B" using a standard tennis racket type closure (i.e., the opening of the bladder neck constituting the head of the tennis racket and a radial incision extending from the bladder

neck constituting the handle portion of the tennis racket. Most preferably, bladder neck "N" is sized to be approximately 7-8 mm in diameter.

With bladder neck "N" reconstructed, apparatus 100, including tubular body 102 and sleeve 104, is passed trans-urethrally through urethra "U" until distal end 110 of tubular body 102 extends out of urethral stump "S" and into bladder "B" through bladder neck "N", as indicated by arrow "A" in FIG. 3. In particular, distal end 110 of tubular body 102 is preferably positioned such that expandable onion sleeve portion 114 of tubular body 102 is positioned entirely within bladder "B". In addition, distal end 130 of sleeve 104 is preferably positioned such that expandable cuff 134 is positioned near urethral stump "S" of urethra "U".

With tubular body 102 positioned within bladder "B", plunger assembly 106 is distally advanced through central lumen 112 of tubular body 102. As described above, as plunger assembly 106 is distally advanced through central lumen 112 of tubular body 102, head portion 144 of plunger assembly 106 first engages the inner surface of ribs 118. As head portion 144 of plunger assembly 106 is further distally advanced, past onion sleeve portion 114, head portion 144 presses ribs 118 radially outward. In so doing, onion sleeve portion 114 is deployed from the biased retracted position to the unbiased expanded position. As such, barbs 122 of ribs 118 of onion sleeve portion 114 become oriented in a substantially proximal direction. Head portion 144 is then further advanced until the coupling element of head portion 144 engages the coupling element formed at distal end 110 of tubular body 102.

With head portion 144 of plunger assembly 106 coupled to distal end 110 of tubular body 102 and onion sleeve portion 114 in the expanded position, either plunger assembly 106 or both plunger assembly 106 and tubular body 102 are pulled in a proximal direction through urethra "U" as indicated by arrows "D". By pulling at least tubular body 102 in a proximal direction, barbs 122 of onion sleeve portion 114 are driven into the wall of bladder "B".

With sleeve 104 positioned near urethral stump "S", a fluid (i.e., air, carbon dioxide, saline or the like) is introduced into cuff 134 to thereby expand and inflate cuff 134. Inflation of cuff 134 results in the radial expansion of cuff 134 and in turn the pressing of cuff 134 against the inner surface of urethra "U", thus preventing axial movement of sleeve 104 through urethra "U".

With onion sleeve portion 114 of tubular body 102 anchored in bladder "B" and cuff 134 of sleeve 104 secured within urethra "U", either tubular body 102, plunger

assembly 106 or both tubular body 102 and plunger assembly 106 are withdrawn in a proximal direction through sleeve 104 in order to approximate bladder "B" to urethra "U". Once bladder "B" has been approximated into contact with urethra "U", tubular body 102 is locked in position with respect to sleeve 104 thereby maintaining bladder "B" approximated with urethra "U". The body 102 may be fixed in relation to sleeve 104 using a latch, or any other known means.

With tubular body 102 fixed in position with respect to sleeve 104, head portion 144 of plunger assembly 106 is disengaged from distal end 110 of tubular body 102 and plunger assembly 106 is withdrawn therefrom. It is envisioned that, with plunger assembly 106 removed from central lumen 112 of tubular body 102, that tubular body 102 and sleeve 104 act like a Foley-type catheter to create a passage, defined by slots 116 and central lumen 112, through which body fluid (i.e., urine) is permitted to pass from bladder "B" and out through urethra "U".

In accordance with the present disclosure, it is preferred that tubular body 102 and sleeve 104 are maintained within bladder "B" and urethra "U" for a period of several weeks or for a period of time sufficient for bladder neck "N" and urethral stump "S" to heal and "grow" together. Once bladder neck "N" and urethral stump "S" have sufficiently healed, and barbs 122 sufficiently dissolved and absorbed within the body, onion sleeve portion 114 and cuff 134 are retracted and tubular body 102 and sleeve 104 are withdrawn from urethra "U".

The expandable anchor for engaging the first and/or second body vessel may comprise any expandable structure, including those disclosed in certain embodiments of the following PCT applications, all filed on an even date herewith: Application Entitled Method And Apparatus For Anastomosis Including An Anchoring Sleeve, invented by Scott Manzo; Method And Apparatus For Anastomosis Including An Anchoring Sleeve, invented by Scott Manzo; Method And Apparatus For Anastomosis Including Annular Joining Member, invented by Scott Manzo; Method And Apparatus For Anastomosis Including Annular Joining Member, invented by Scott Manzo; Method And Apparatus For Anastomosis Including An Expandable Member, invented by Russell Heinrich and Scott Manzo; Method And Apparatus For Anastomosis Including An Expandable Anchor, invented by Russell Heinrich and Scott Manzo (Ref. No. 2798); the disclosures of which are all hereby incorporated by reference herein, in their entirety.

The joining member for joining the first and/or second body vessel may comprise any joining member, including those disclosed in certain embodiments of the following

PCT Applications: Method And Apparatus For Anastomosis Including An Anchoring Sleeve, invented by Scott Manzo; Method And Apparatus For Anastomosis Including Annular Joining Member, invented by Scott Manzo; Method And Apparatus For Anastomosis Including Annular Joining Member, invented by Scott Manzo; Method And
5 Apparatus For Anastomosis Including An Anchor For Engaging A Body Vessel And Deployable Sutures, invented by Scott Manzo; Method And Apparatus For Anastomosis Including An Anchor For Engaging A Body Vessel And Deployable Sutures, invented by Scott Manzo; Method And Apparatus For Anastomosis Including An Expandable Member, invented by Russell Heinrich and Scott Manzo; Method And Apparatus For
10 Anastomosis Including An Expandable Anchor, invented by Russell Heinrich and Scott Manzo; the disclosures of which are all hereby incorporated by reference herein, in their entirety.

Turning now to FIGS. 7 and 8, an anastomosis apparatus, in accordance with an alternative embodiment of the disclosure, is shown generally as reference numeral 200.
15 Apparatus 200 includes a tubular body 202, a sleeve 204 slidably received about tubular body 202 and a plunger assembly 206 slidably received within tubular body 202. Tubular body 202 includes a distal end 210 and a proximal end (not shown) and defines a central lumen 212 extending therethrough which central lumen 212 defines a central longitudinal axis "X".

20 Tubular body 202 includes an expandable onion sleeve portion 214 formed near distal end 210. In accordance with the present disclosure, onion sleeve portion 214 includes a plurality of radially formed, longitudinally oriented, elongated slots 216. Slots 216 define a plurality of longitudinally oriented ribs 218, each having a plurality of transverse flexure lines 220 formed along the length thereof. Preferably, each rib 218
25 includes a distal flexure line 220A, a proximal flexure line 220B, a pair of central flexure lines 220C, 220D, a first intermediate flexure line 220E formed between distal flexure line 220A and central flexure line 220C and a second intermediate flexure line 220F formed between proximal flexure line 220B and central flexure line 220D.

In accordance with the present disclosure, flexure lines 220A-220F are configured
30 and adapted such that onion sleeve portion 214 has a retracted position, as seen in FIG. 6, in which a radius of onion sleeve portion 214, about first intermediate flexure lines 220E, is less than a radius of tubular body 202. Onion sleeve portion 214 has an unbiased position, as seen in FIG. 7, in which the radius of onion sleeve 214, about intermediate flexure lines 220E, is greater than the radius of the tubular body 202. Preferably, when

onion sleeve portion 214 is in the expanded position, the portion of each rib 218 between first intermediate flexure line 220E and central flexure line 220C is orthogonal with respect to the longitudinal "X" axis. Further, when onion sleeve portion 214 is in the expanded position, the portion of each rib 218 between second intermediate flexure 220F and central flexure line 220D is orthogonal with respect to the longitudinal "X" axis.

Onion sleeve portion 214 of tubular body 202 further includes at least one barb 222 extending outwardly from each rib 218. Preferably, the at least one barb 222 is provided on the portion of rib 218 between first intermediate flexure line 220E and central flexure line 220C. Preferably, first intermediate flexure line 220E is a double articulating flexure line. Accordingly, when onion sleeve portion 214 is in the retracted position, barbs 222 do not extend beyond the radial boundary of tubular sleeve 202. In this manner, barbs 222 do not interfere with the passage of tubular body 202 through sleeve 204. Further, in accordance with the present disclosure, when onion sleeve portion 214 is in the expanded position, it is preferred that barbs 222 are oriented substantially in a proximal direction and are substantially parallel with the longitudinal "X" axis.

As seen in FIGS. 6 and 7, distal end 210 of tubular body 202 is provided with a blunt end cap 224. However, it is envisioned that tubular body 202 can have a distal end 210 which opens into central lumen 212.

Sleeve 204 includes a distal end 230 and a proximal end (not shown) defining a lumen 232 extending therethrough. It is envisioned that distal end 230 of sleeve 204 can be tapered in order to facilitate passage of sleeve 204 through the body lumen. In accordance with the present disclosure, sleeve 204 includes an expandable cuff 234 provided near distal end 230 thereof. Preferably, expandable cuff 234 has a first position in which expandable cuff 234 has a radius which is less than or equal to a radius of sleeve 204 and a second position in which expandable cuff 234 has a radius which is greater than the radius of sleeve 204.

It is envisioned that sleeve 204 is provided with an inflation/deflation lumen (not shown) extending along the length thereof and which is in fluid communication with expandable cuff 234 through at least one access opening (not shown) formed in sleeve 204. In use, the inflation/deflation lumen is coupled to a source of inflation fluid (not shown) and a fluid is injected through the inflation/deflation lumen in order to inflate and expand cuff 234 to an expanded condition and thereby anchor or fix the placement of sleeve 204 within the body lumen. Concomitantly, withdrawal of the fluid used to inflate

and expand cuff 234 will cause cuff 234 to deflate and thereby allow sleeve 204 to be withdrawn from the body lumen.

It is contemplated that at least one annular seal, i.e., an O-ring, (not shown) may be provided between tubular body 202 and sleeve 204. Accordingly, it is envisioned that
5 the annular seal prevents or reduces the possibility of fluids from passing between tubular body 202 and sleeve 204.

Plunger assembly 206 includes a shaft 240 having a distal end 242, a proximal end (not shown) and a head portion 244 operatively coupled to distal end 242. In accordance with the present disclosure, head portion 244 is preferably dimensioned to be received
10 within central lumen 212 of tubular body 202. More preferably, head portion 244 defines a circular outer surface having an outer radius slightly smaller than the inner radius of tubular body 202

It is envisioned that the outer surface of head portion 244 is provided with a coupling element, similar to coupling element of head portion 144, configured and
15 adapted to engage a corresponding coupling element formed in either the inner surface of the distal end 210 of tubular body 202 or on the inner surface of end cap 224 of tubular body 202.

In use, as plunger assembly 206 is distally advanced through central lumen 212 of tubular body 202, head portion 244 of plunger assembly 206 first engages the inner
20 surface of ribs 218. As head portion 244 of plunger assembly 206 is further distally advanced, past onion sleeve portion 214, head portion 244 presses ribs 218 radially outward. In so doing, onion sleeve 214 goes from the biased retracted position to the unbiased expanded position, as discussed above. Head portion 244 is then further advanced until the coupling element of head portion 244 engages the coupling element
25 formed at distal end 210 of tubular body 202. In other embodiments, other means are used to deploy the onion sleeve portion.

It is envisioned that apparatus 200 be provided with a locking mechanism for securing tubular body 202 to sleeve 204 and to prevent their relative movement with respect to one another. The body 202 and sleeve 204 may be secured using latch or any
30 other means.

With bladder neck "N" reconstructed, apparatus 200, including tubular body 202 and sleeve 204, is passed trans-urethrally through urethra "U" until distal end 210 of tubular body 202 extends out of urethral stump "S" and into bladder "B" through bladder neck "N". In particular, distal end 210 of tubular body 202 is preferably positioned such

that first intermediate flexure line 220E is positioned distally of bladder neck “N” and second intermediate flexure line 220F is positioned proximally of bladder neck “N”. In addition, distal end 230 of sleeve 204 is preferably positioned such that expandable cuff 234 is positioned near urethral stump “S” of urethra “U”.

5 With tubular body 202 so positioned with respect to bladder neck “N”, plunger assembly 206 is distally advanced through central lumen 212 of tubular body 202. As described above, as plunger assembly 206 is distally advanced through central lumen 212 of tubular body 202, head portion 244 of plunger assembly 206 first engages the inner surface of ribs 218, in particular, the inner surface of ribs 218 disposed between first
10 intermediate flexure line 220E and central flexure line 220C. As head portion 244 of plunger assembly 206 is further distally advanced, past onion sleeve portion 214, head portion 244 presses ribs 118 radially outward. In so doing, onion sleeve portion 214 is deployed from the retracted position to the expanded position. As such, barbs 222 of ribs 218 of onion sleeve portion 214 become oriented in a substantially proximal direction.
15 Head portion 244 is then further advanced until the coupling element of head portion 244 engages the coupling element formed at distal end 210 of tubular body 202.

 With head portion 244 of plunger assembly 206 coupled to distal end 210 of tubular body 202 and onion sleeve portion 214 in the expanded position, shaft 240 of plunger assembly 206 is pulled in a proximal direction through tubular body 202, while
20 holding tubular body 202 in a fixed position. By pulling shaft 240 in a proximal direction and holding tubular body 202 in a fixed position, second intermediate flexure line 220F of onion sleeve portion 214 is expanded radially outward.

 With barbs 222 oriented in a proximal direction, as shaft 240 is pulled in a proximal direction, onion sleeve portion 214, being a double onion, acts like a clamp to
25 close down about bladder neck “N”. In so doing, barbs 222 are driven through bladder neck “N” while rib 218, between central flexure line 220D and second intermediate flexure line 220F, acts to support the exterior surface of bladder neck “N”. It is envisioned that the portion of each rib 218, between central flexure line 220D and second intermediate flexure line 220F, is provided with an opening for accommodating passage
30 of barbs 222 therethrough during the clamping process. With barbs 222 anchored in the wall of bladder neck “N”, shaft 240 of plunger assembly 206 is moved in a proximal direction, with respect to tubular body 202, in order to return second intermediate flexure line 220F to the retracted position.

With sleeve 204 positioned near urethral stump "S", a fluid is introduced into cuff 234 to thereby expand and inflate cuff 234. Inflation of cuff 234 results in the radial expansion of cuff 234 and in turn the pressing of cuff 234 against the inner surface of urethra "U", thus preventing axial movement of sleeve 204 through urethra "U".

5 With onion sleeve portion 214 of tubular body 202 anchored in bladder "B" and cuff 234 of sleeve 204 secured within urethra "U", either tubular body 202, plunger assembly 206 or both tubular body 202 and plunger assembly 206 are withdrawn in a proximal direction through sleeve 204 in order to approximate bladder "B" to urethra "U". Once bladder "B" has been approximated into contact with urethra "U", tubular
10 body 202 is locked in position with respect to sleeve 204 thereby maintaining bladder "B" approximated with urethra "U".

 With tubular body 202 fixed in position with respect to sleeve 204, head portion 244 of plunger assembly 206 is disengaged from distal end 210 of tubular body 202 and plunger assembly 206 is withdrawn therefrom. In accordance with the present disclosure,
15 it is preferred that tubular body 202 and sleeve 204 are maintained within bladder "B" and urethra "U" for a period of several weeks or for a period of time sufficient for bladder neck "N" and urethral stump "S" to heal and "grow" together. Once bladder neck "N" and urethral stump "S" have sufficiently healed, and barbs 222 sufficiently dissolved and absorbed within the body, onion sleeve portion 214 and cuff 234 are retracted and tubular
20 body 202 and sleeve 204 withdrawn from urethra "U".

 While apparatus in accordance with the present disclosure have been described as being used in connection with radical prostatectomy procedures, it is envisioned that apparatus having similar structures and modes of operation can be used in various other surgical procedures. It will be understood that various modifications may be made to the
25 embodiments of the presently disclosed anastomosis devices and methods disclosed herein. For example, the onion sleeve portion may be deployable by other means. One end of the ribs may be attached to a sleeve that is moved proximally, bending the ribs outwardly. In other embodiments, the body has arms that are deployed outwardly by the head portion of the plunger assembly or by some other means. Therefore, the above
30 description should not be construed as limiting, but merely as an exemplification of a preferred embodiment. Those skilled in the art will envision other modifications within the scope of the present disclosure.

IN THE CLAIMS

What is claimed is:

1. An apparatus for joining a first body vessel and a second body vessel, comprising:
 - 5 a) a tubular body having a proximal end, a distal end, and an onion portion formed near the distal end of the tubular body for engaging the first body vessel, the onion portion having a first position within a radial dimension of the tubular body and a second position outside the radial dimension of the tubular body;
 - b) a sleeve having an expandable cuff for engaging the second body vessel,
10 the sleeve having a lumen for receiving the tubular body; and
 - c) a plunger assembly for being received in the tubular body, the plunger assembly having a distal end arranged for deploying the onion portion from the first position to the second position.
- 15 2. The apparatus of claim 1, wherein the onion portion comprises a plurality of ribs defining a plurality of longitudinally oriented slots.
3. The apparatus of claim 2, wherein each of the ribs has at least one flexure line defined therein.
20
4. The apparatus of claim 3, wherein each of the ribs has a proximal flexure line, a distal flexure line, and an intermediate flexure line defined therein.
5. The apparatus of claim 4, wherein the intermediate flexure line comprises
25 a double articulating joint.
6. The apparatus of claim 1, wherein the onion portion has a plurality of barbs for engaging the first body vessel, the barbs being arranged to face in a proximal direction when the onion portion is in the second position.
30
7. The apparatus of claim 1, wherein the onion portion has at least one expanded portion disposed outside the radial dimension of the tubular body when the onion portion is in the second position for engaging the first body vessel.

8. The apparatus of claim 7, wherein the onion portion has a pair of expanded portions disposed outside the radial dimension of the tubular body when the onion portion is in the second position for engaging the first body vessel between the pair of expanded portions.

5

9. The apparatus of claim 8, wherein the onion portion comprises a plurality of ribs, each of the ribs having a proximal flexure line, a distal flexure line, a pair of central flexure lines, a first intermediate flexure line between the central flexure lines and the distal flexure line, and a second intermediate flexure line between the central flexure lines and the proximal flexure line.

10

10. The apparatus of claim 9, wherein the first and second intermediate flexure line comprise double articulating joints.

15

11. The apparatus of claim 10, wherein the onion portion defines a radius about the first and second intermediate flexure lines that is less than the radial dimension of the tubular body.

20

12. The apparatus of claim 1, wherein the distal end of the plunger assembly has an engaging element adapted to selectively couple with an engaging element provided at the distal end of the tubular body.

13. A method of joining a first body vessel and a second body vessel, comprising:

25

a) passing an apparatus through the second body vessel, the apparatus having a tubular body and an onion portion, so that the onion portion is received in the first body vessel;

b) deploying the onion portion so that the onion portion moves to a position outside the radial dimension of the tubular body; and

30

c) approximating and joining the first body vessel and the second body vessel.

14. The method of claim 13, wherein the step of approximating includes deploying an expandable cuff so as to engage the second body vessel.

15. The method of claim 14, wherein onion portion being disposed on the tubular body, and a sleeve, the sleeve having the expandable cuff, and the method further comprises moving the tubular body and the sleeve with respect to one another so as to approximate the first and second body vessels.

16. The method of claim 13, wherein the apparatus has a tubular body, the onion portion being disposed on the tubular body, and a plunger assembly for deploying the onion portion, and wherein the method includes advancing the plunger assembly so as to deploy the onion portion.

17. The method of claim 15, further comprising securing the position of the tubular body and sleeve with respect to one another.

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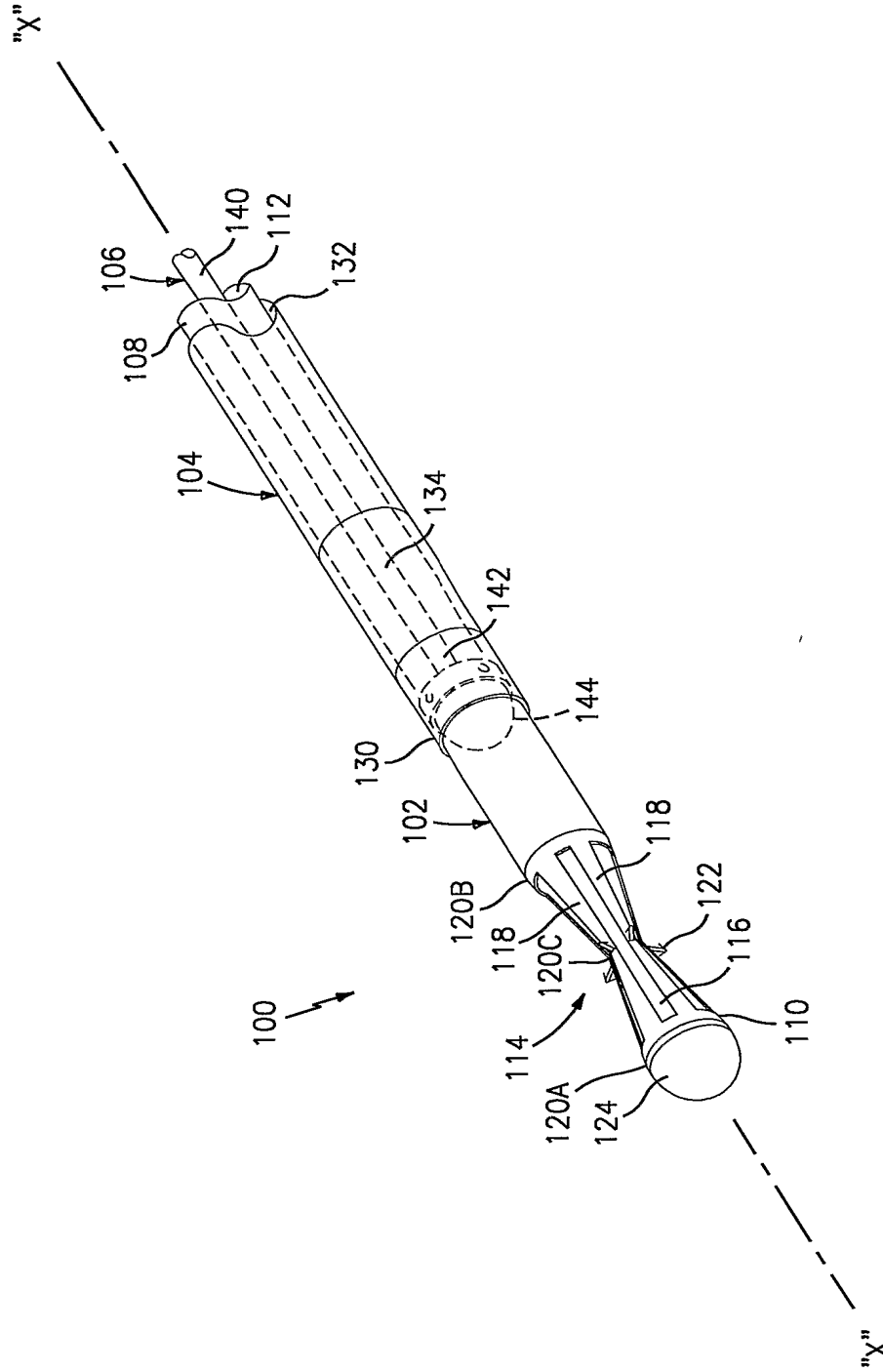


FIG. 1

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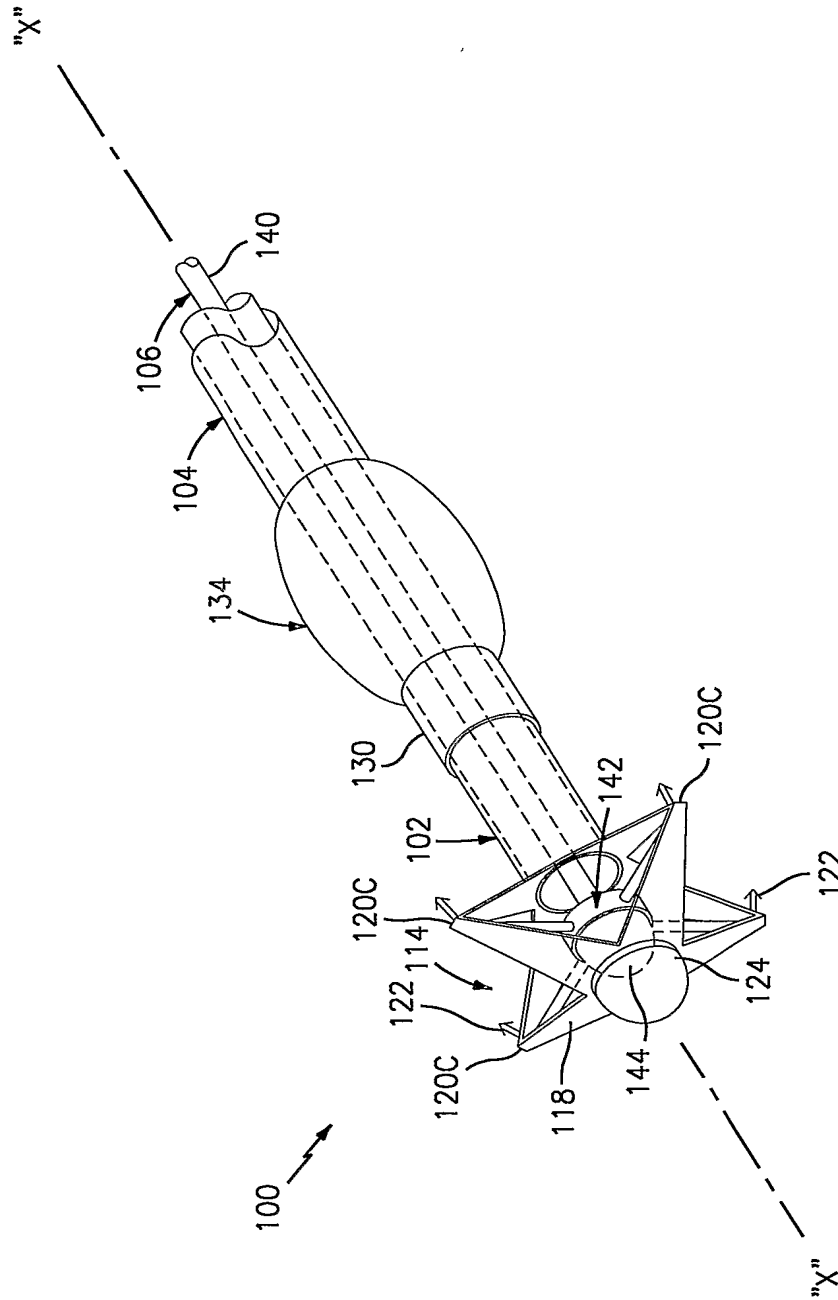


FIG. 2

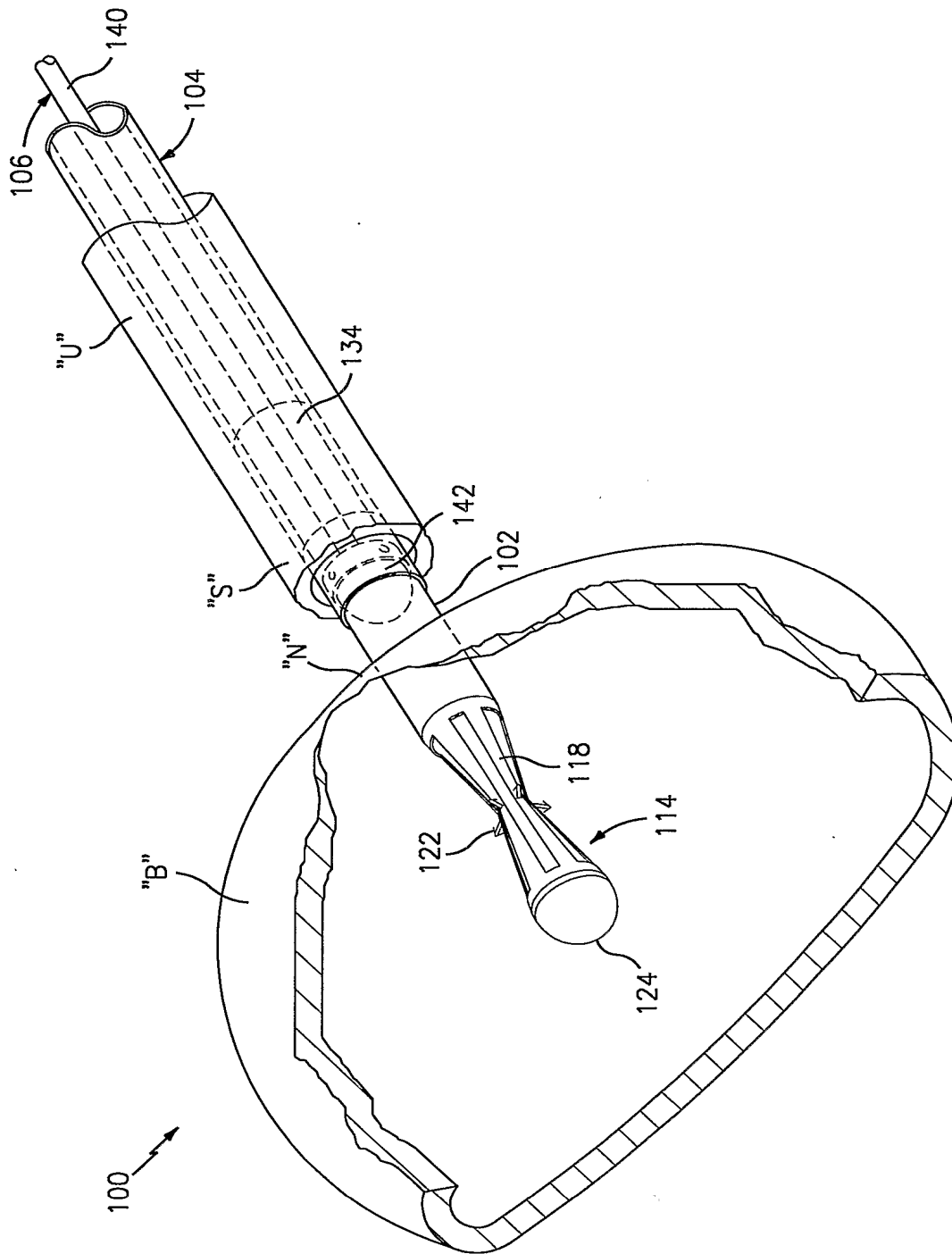


FIG. 3

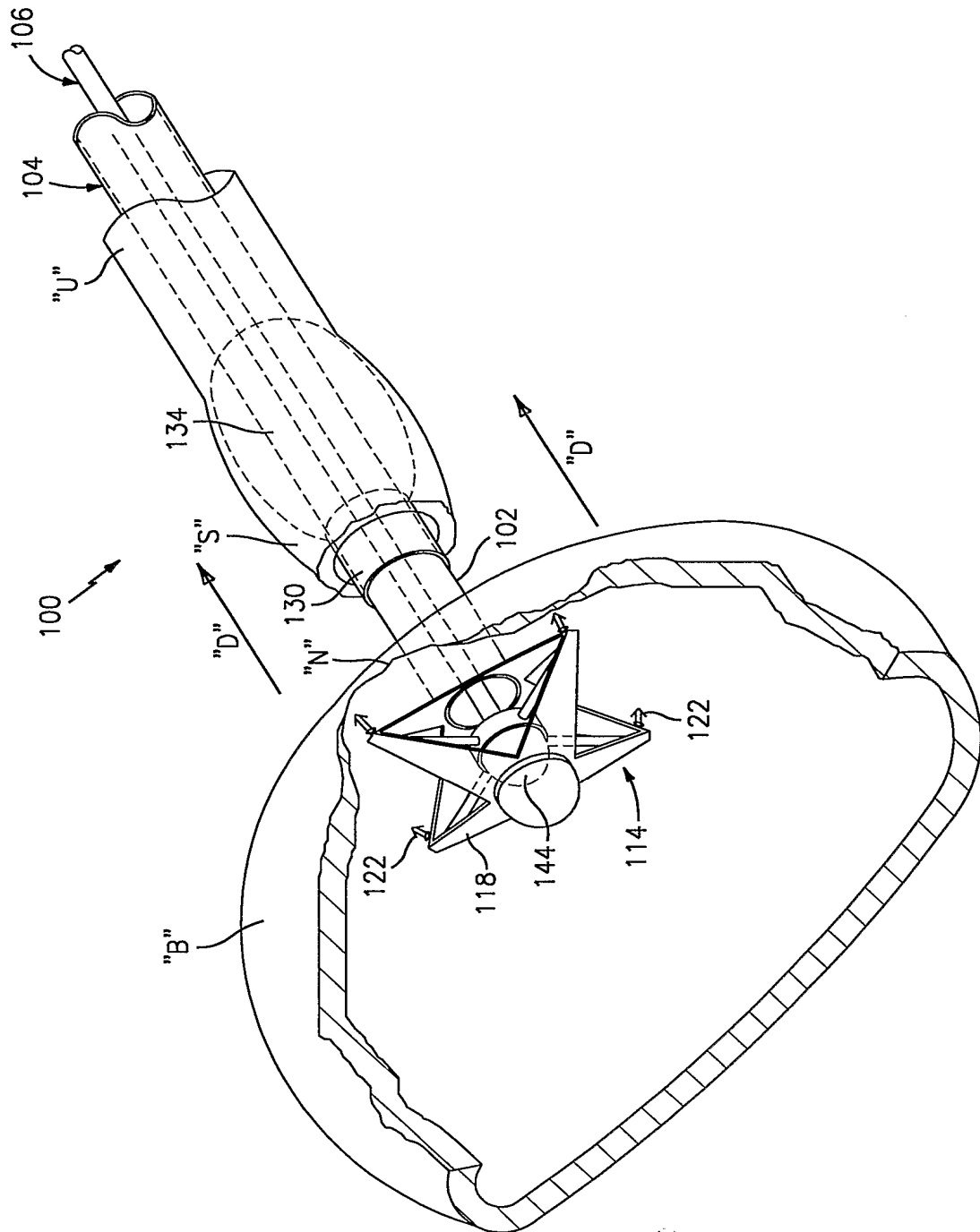


FIG. 4

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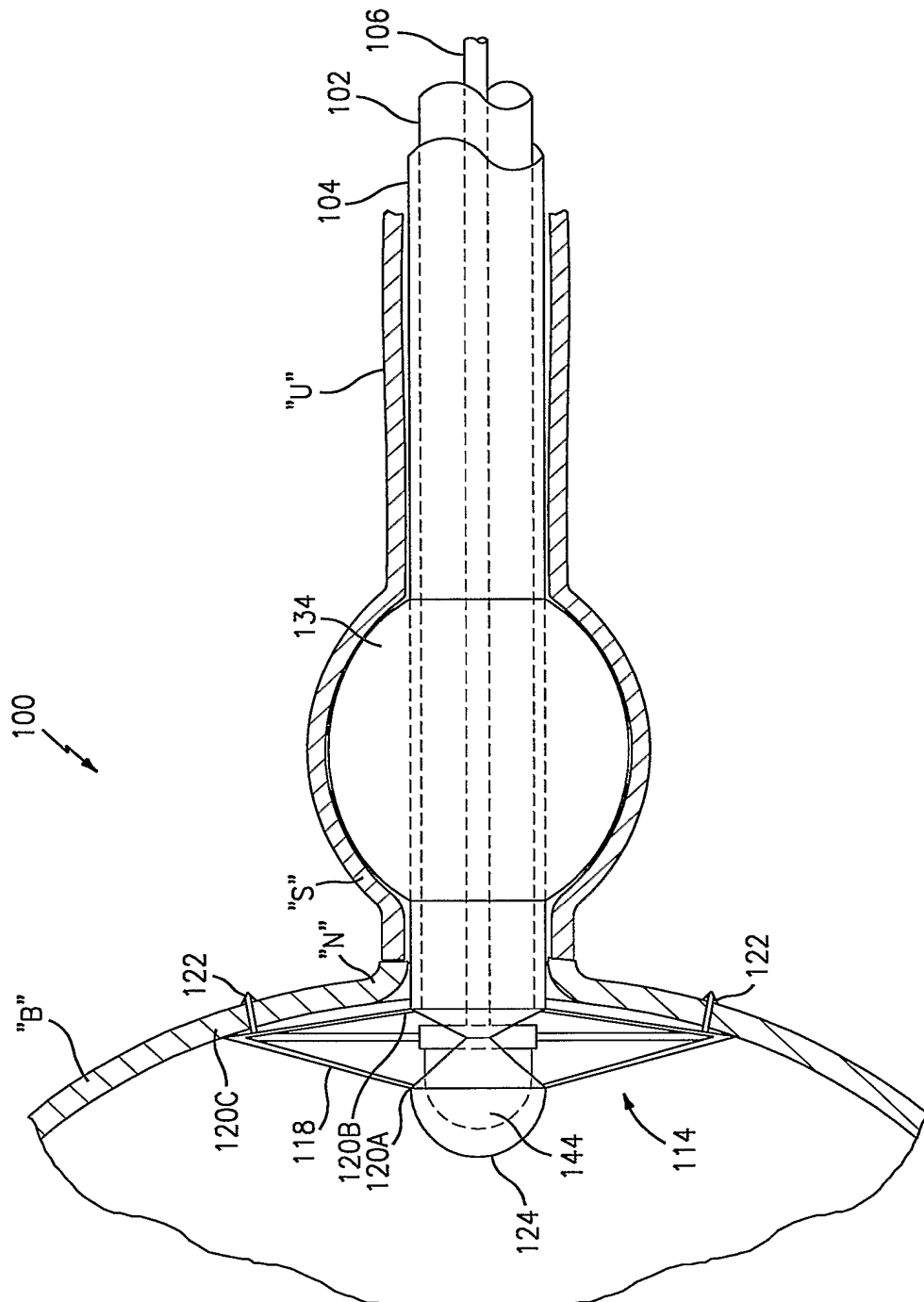


FIG. 5

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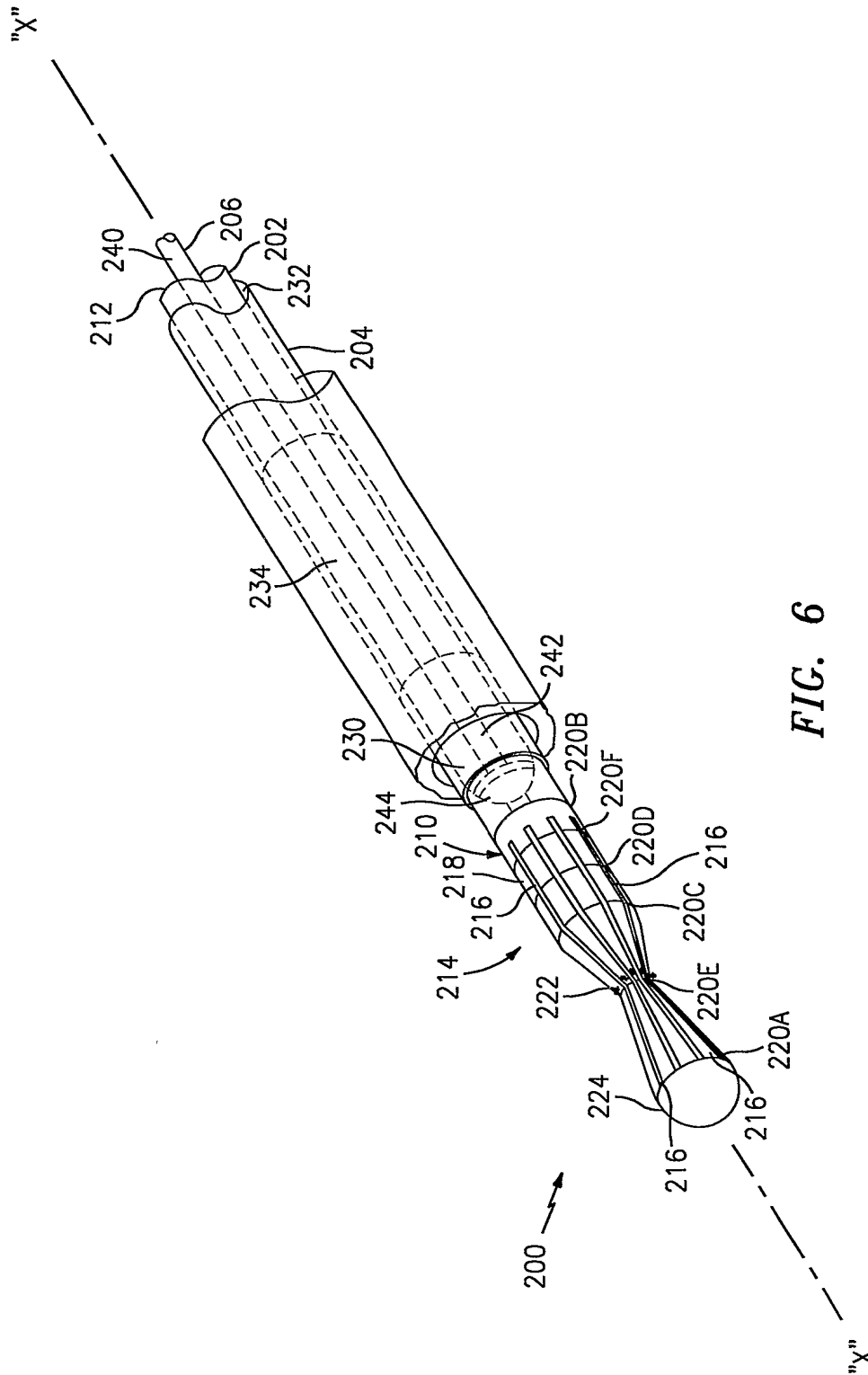


FIG. 6

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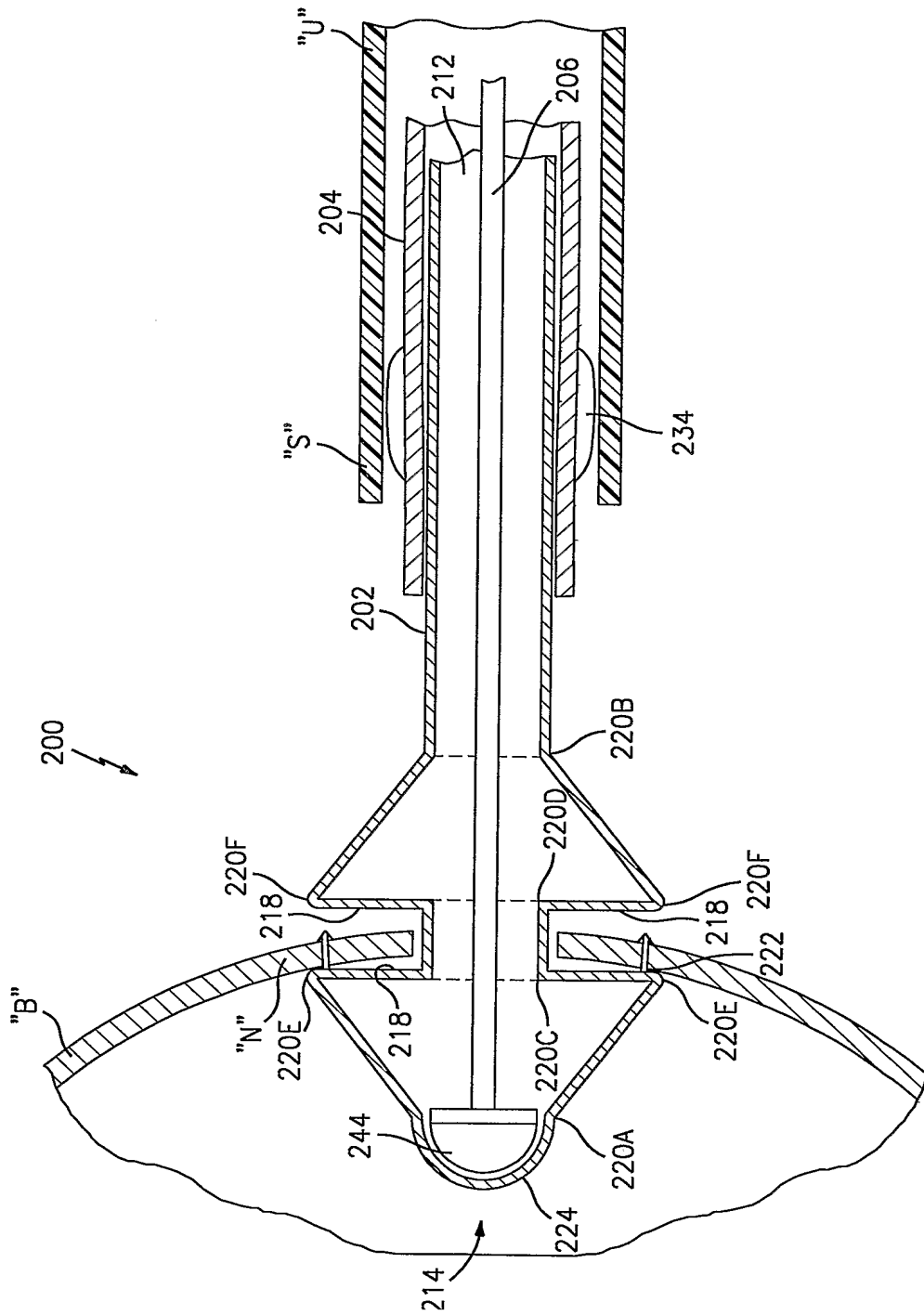


FIG. 7

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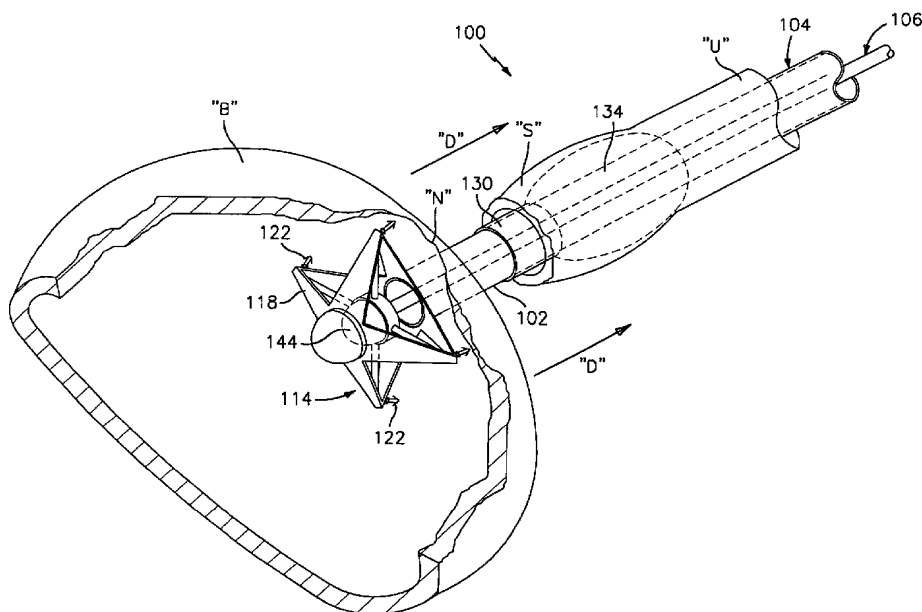
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15 April 2004

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(54) Title: METHOD AND APPARATUS FOR ANASTOMOSIS INCLUDING AN ANCHORING SLEEVE



(57) Abstract: Apparatus for performing a surgical anastomosis include a tubular body (102) having an onion portion (114) formed near the distal end of the tubular body. The apparatus includes a sleeve (104) having a radius sized and dimensioned to slidably receive the tubular body therein. The apparatus includes a plunger assembly sized and dimensioned to be slidably received within the central lumen of the tubular body. The plunger assembly includes a distal end configured and adapted to deploy the onion portion.



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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/11691

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 245 083 B1 (BLACK KIRBY S ET AL) 12 June 2001 (2001-06-12) column 8, line 4 - line 8 -----	1



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

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Date of the actual completion of the international search

3 December 2003

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/11691

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 13-17
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No

PCT/US 03/11691

Patent document cited in search report		Publication date		Patent family member(s)		Publication date	
US 6245083	B1	12-06-2001	US	2002138098 A1		26-09-2002	